

Remarks

Status of the claims

Claims 30 and 44 have been amended to recite the phrase “of SEQ ID NO:2,” as well as, to remove reference to Reiter’s Disease, Guillain-Barre Syndrome, Hashimoto's thyroiditis, Addison's disease, and biliary cirrhosis without prejudice or disclaimer. In addition, Claims 43 and 57 have been amended to replace “Hashimoto's thyroiditis” with “asthma.” Finally, Claims 38-39 and 52-53 have been canceled without prejudice or disclaimer. Applicants reserve the right to pursue subject matter encompassed by all canceled claims or deleted subparts of claims in one or more divisional or continuation applications. No new matter has been added by these amendments. Upon entry of these amendments, claims 30-37, 40-51, and 54-57 will be pending.

Applicants have also amended the Title, the first paragraph of the specification, and the Abstract as requested by the Office. Accordingly, no new matter has been added.

Objections to the Specification

The Office has objected to the specification alleging the following informalities: (1) that the abstract does not adequately describe the claimed invention, and (2) the Title of the invention is not descriptive. *See*, Paper No. 20070623, page 3. Applicants respectfully disagree and traverse this objection.

Nonetheless, to expedite prosecution, Applicants have amended the abstract to include a more specific reference to the claimed invention, in addition to amending the Title as suggested by the Office. Accordingly, Applicants respectfully request that objection to the specification on the grounds that the abstract does not adequately describe the invention and/or that the Title does not describe the invention be reconsidered and withdrawn.

Priority & Pertinent Art

Applicants wish to thank the Office for the reminder to update the status of all applications recited in the first paragraph of the specification to which the instant

application claims benefit of priority, as required by 37 CFT 1.78. As requested by the Office, Applicants have updated the status of US Application 09/848,271.

In addition, Applicants agree with the Office that the instant application is entitled to priority to US Provisional Application 60/301,852, filed May 4, 2000. *See*, Paper No. 20070623, pages 3-4, item 5.2. Further, Applicants agree that the specification enables claims to “a method of treating Sjogren’s syndrome using a polypeptide 90% identical to a polypeptide comprising amino acids 4-44, 4-52, 4-54, 8-41, 1-54, and the extracellular domain of the TR18 receptor polypeptide of SEQ ID NO:2.” *Id.* at page 5, item 6. However, Applicants disagree that the instant application is not enabled for the treatment of for example, asthma (see below). In addition, while it could be argued contrary to the Office’s assertion that WO/01/12812 discloses TR18 binding to neutrokin-alpha earlier than Marsters et al. (see, Paper No. 20070623, page 6), Applicants respectfully submit that neither of these references teach a method for using antibodies of the invention for treating Sjogren’s syndrome or asthma.

Rejection of Claims 30-41, 43-55, and 57 under 35 U.S.C. § 112, First Paragraph

The Office has rejected claims 30-41, 43-55, and 57 under 35 U.S.C. § 112, First Paragraph for allegedly not enabling any person skilled in the art to use the invention. In particular the Office asserts:

“while being enabling for a method of treating Sjogren’s Syndrome with a polypeptide that is 90% identical to a polypeptide comprising amino acids 4-44, 4-52, 4-54, 8-41, 1-54, and the extracellular domain of TR18 receptor polypeptide of SEQ ID NO:2, [the specification] does not reasonably provide enablement for treatment of any other autoimmune disease or condition ... the specification and the art do not disclose whether neutrokin-alpha is overexpressed in any other autoimmune disease or condition associated with an autoimmune disease, such that the diseases or conditions in the claims could be treated with the claimed polypeptides.” *See*, Paper No. 20070623, pages 4-5, item 6.

Applicants respectfully disagree and traverse.

As a preliminary matter, Applicants respectfully note that reference to Reiter’s Disease, Guillain-Barre Syndrome, Hashimoto’s thyroiditis, Addison’s disease, and biliary cirrhosis in claims 30 and 44 has been removed without prejudice or disclaimer.

Accordingly, Applicants respectfully submit that rejection of claims 30-41, 43-55, and 57 on the basis of reciting Reiter's Disease, Guillain-Barre Syndrome, Hashimoto's thyroiditis, Addison's disease, and biliary cirrhosis should be reconsidered and withdrawn. Moreover, Applicants have canceled claims 38-39 and 52-53 without prejudice or disclaimer. Accordingly, Applicants respectfully submit that the Office's rejection of claims 38-39 and 52-53 for alleged lack of enablement is moot.

Applicants respectfully disagree with the Office's assertion that "the specification and the art do not disclose whether neutrokin-alpha is overexpressed in any other autoimmune disease or condition associated with an autoimmune disease, such that the diseases or conditions in the claims could be treated with the claimed polypeptides." *See*, Paper No. 20070623, page 5, item 6.

For example, paragraph 0331 of the specification states "an individual having an autoimmune disease or disorder may express aberrantly high levels of Neutrokin-alpha, APRIL, and/or TR18 when compared to an individual not having an autoimmune disease or disorder." In addition, paragraph 0330 lists several autoimmune diseases or conditions associated with autoimmune diseases, including Sjogren's Syndrome and asthma, that may be treated with polypeptides of the invention. In addition, the Office agrees that several references teach that neutrokin-alpha is overexpressed and correlates with autoantibodies in Sjogren's Syndrome. *See*, Paper No. 20070623, page 5, item 6. Applicants respectfully submit that several additional references also teach that neutrokin-alpha levels are elevated in asthma patients (*See*, **Exhibit 1**) and that asthmatic symptoms are alleviated by scavenging BAFF in a mouse asthma model (*See*, **Exhibit 2**).

Accordingly, Applicants respectfully request that rejection of claims 30-41, 43-55, and 57 under 35 U.S.C. § 112, First Paragraph for allegedly not enabling any person skilled in the art to use the invention be reconsidered and withdrawn.

Conclusion

Applicants respectfully request that the amendments and remarks submitted herein be entered in the present application. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the examination of this application.

If there are any fees not already accounted for due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the fee should also be charged to our Deposit Account.

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Respectfully submitted,

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